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Philippines

Biotechnology - GE Plants and Animals

Philippine Biotechnology Situation and Outlook

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Report Highlights:

The Philippine biotechnology regulatory system continues to evolve but remains science-based. Commercialization of the first locally developed genetically enhanced crop is expected late 2011 or early 2012. There have been no reported biotechnology-related disruptions in 2009 and the country continues to be the agricultural biotechnology model in the region. A newly elected government officially assumed office in July 1, 2010. Although specific policy directions relative to agricultural biotechnology are still unknown, Post does not expect any significant deviation in overall Philippine agricultural policy.

Section I. Executive Summary:

The Philippine biotechnology regulatory system continues to evolve but remains science-based. Under the current regulatory regime as provided for by the Philippine Department of Agriculture's Administrative Order No. 8 (DA-AO 8), 31 transformation events (TEs) and 22 stacked-trait products have been approved for direct use as food, feed or propagation. There remains to be five (5) biotech crop varieties approved for propagation while 11 field tests have been allowed since 2004. Guided by DA-AO 8, the first genetically enhanced (GE) crop being developed locally, *Bacillus thuringiensis* (Bt) eggplant, will likely be commercialized by the second semester of 2011 or early 2012.

With regards to trade, there have been no reported biotechnology-related disruptions in 2009. Because the Philippines is both a technology-developer as well as a technology-user, it adopts the unique position of both perspectives in current liability and redress (L & R) discussions under the Cartagena Protocol on Biosafety (CPB).

The Philippine biotechnology regulatory regime has earned the country leadership-status in the region. This is manifest in the increasingly frequent visits of foreign delegations interested in the local biotechnology regulatory system. Although there are isolated pockets of resistance, the overall support on the responsible use of modern agricultural biotechnology remains strong.

Agricultural policy is intimately intertwined with politics in the Philippines and a newly elected government officially assumed office on July 1, 2010. President-elect Benigno Aquino III is perceived to be pragmatic and in general terms, Post does not expect any significant deviation in overall Philippine agricultural policy. Specific policy directions relative to modern agricultural biotechnology, however, are still unknown.

Section II. Plant Biotechnology Trade and Production:

As of May 4, 2010, there were four (4) TEs approved for commercial production in the Philippines, namely: Monsanto's Corn MON810 and Corn NK 603; and Syngenta's Corn Bt 11 and Corn GA 21 (see Appendix A). There remains to be one (1) stacked or combined trait corn variety (Monsanto's Corn MON810 x Corn NK603) approved for propagation making 5 the total GE crop varieties that may be cultivated commercially.

In 2009, the Philippine Bureau of Plant Industry (BPI) estimates the total area planted to GE corn at 327,226 hectares, slightly lower than the 347,575 hectares planted in 2008. Excessive rainfall and flooding in the main island of Luzon in late 2009 discouraged corn cultivation during the period. This year, no significant growth in GE corn seed use is expected due to extreme dryness and scarcity of irrigation water brought about by an El Nino weather disturbance in the first half of 2010.

ACCIDECATE DATA OF CM CODN (bases)			
AGGREGATE DATA OF GM CORN (hectares)		1	

			Bt*corn				
Island Group	2003	2004	2005	2006	2007	2008	2009
LUZON	10,158	48,516	43,735	85,702	103,438	68,301	38,507
VISAYAS	24	534	445	405	2,551	298	0
MINDANAO	587	10,706	5,829	10,693	16,604	13,053	9,516
Total	10,769	59,756	50,009	96,800	122,593	81,652	48,023
			RR**	Corn			
LUZON				11,685	54,509	5,471	3,518
VISAYAS				4,424	8,925	4,571	2,790
MINDANAO				10,384	56,589	41,443	40,501
Total				26,493	120,023	51,485	46,809
			Stacked (Bt + RR)			
LUZON				3,879	59,346	158,520	183,771
VISAYAS				232	2,472	7,074	8,006
MINDANAO				469	9,461	48,844	40,618
Total				4,580	71,279	214,438	232,395
GRAND TOTAL	10,769	59,756	50,009	127,873	313,895	347,575	327,226

^{*}Bt-Bacillus thuringiensis

The latest list of regulated articles approved for field testing is provided in the following table. Since 2004, 11 GE crop field trials have been approved, for a slight increase from the nine (9) approved field tests reported in the previous annual report (GAIN RP 9030).

as of March 24, 2010 Proposal Technology Date						
Tioposai	Developer	Approved				
Demonstration of Weed Control	Monsanto	11/26/04				
Performance of Roundup Ready Corn						
(RRC) System DK818 NK603						
vis-à-vis Farmers' Practices						
2. Performance of Roundup Herbicide	Monsanto	11/26/04				
(360 g ae/L IPA Salt) Against Weeds in						
Glyphosate-Tolerant Corn						
3. Field Verification of the Agronomic	Monsanto	12/10/04				
Performance of the Transgenic Corn (zea mays L.) Hybrid Stacked						
(NK603/MON 810) Expressing the Bacillus Thuringiensis Cry1AB						
Protein for Resistance Against the Asiatic Corn Borer (Ostrinia						

^{**}RR – Roundup Ready

fumacalis Guenee) and CP4 EPSPS for Tolerance Gainst the		
Herbicide		
Roundup		
4. Performance of Heculex 1 Bt Transgenic Corn	Dow Sciences	05/02/06
Hybrids against Asiatic Corn Borer (Ostrinia		
fumacalis Guenee) under field conditions in the		
Philippines		
5. Field Testing of Transgenic Papaya with delayed Ripening Trait	University of the Philippines at Los Banos	03/20/07
6. Multi-location Field Efficacy Verification Trial	Syngenta	11/19/07
of Herbicide Tolerant Maize Expressing Event GA21 Against		
Glyphosate Herbicide in the Philippines		
7. Agronomic Equivalency Trial of MON89034	Monsanto	08/01/08
Hybrids with Regulatory Framework in the Philippines		
8. Field Verification of the Agronomic Performance of Transgenic Corn (<i>Zea mays</i> L.) line MON89034 Expressing the <i>Bacillus thuringiensis</i> Cry1A.105 and Cry2Ab Proteins for Efficacy Against Lepidopterous Pests of Corn	Monsanto	08/01/08
9. Field Verification of the Agronomic Performance of Stacked Hybrid Corn (<i>Zea mays</i> L.) MON89034 x NK603 Expressing the <i>Bacillus Thuringiensis</i> Cry1A.105 and Cry2Ab2 Proteins for Efficacy against Lepitopterous Pests of Corn and CP4EPSPS for tolerance of Round up Herbicide	Monsanto	08/01/08
10. Multi-location Field Efficacy Trial of Corn Hybrid Expressing the Stacked Trait Bt11 x GA21 Against the Asiatic Corn Borer and Glyphosate Herbicide in the Philippines	Syngenta	10/28/09
11. Development and Commercialization of Philippine Fruit and Shoot Borer Resistant Eggplants Containing MAHYCO Bt eggplant event, EE-1. Multi-location Field Trials for Biosafety Assessment, Variety Accreditation and Fertilizer and Pesticide Authority Registration	University of the Philippines at Los Banos	03/16/10

Local scientists expect the fruit-and-shoot-borer-resistant (FSBR) eggplant to be the first locally developed GE-crop to be commercialized by the second semester of 2011 or early 2012. Eggplant is widely consumed in the Philippines and its development is a public sector led initiative. With the Institute of Plant Breeding at the University of the Philippines at Los Banos (IPB-UPLB) as its registered developer, the FSBR eggplant is currently on the multi-location trials stage to test its viability in different parts of the Philippines. The recent decision by India's Environment Ministry to put on hold the commercial approval of its Bt eggplant application is not expected to affect the local approval process of the FSBR project. What happened in India is not a legal impediment to the

approval of the local FSBR eggplant should it be found worthy of commercialization, according to industry contacts.

The golden rice project is not listed in the field-testing approval registry for field tests as it is under the supervision of the National Committee on Biosafety of the Philippines. The project is being conducted at the Philippine Rice Research Institute compound. Barring any untoward event, the earliest time for its commercial release would be late 2012 or early 2013. On, the other hand, the commercialization of the virus-resistant papaya with a delayed ripening trait will be delayed. It is currently in the contained-trial stage and upon completion, will be field-tested in several locations. The earliest time it will be ready for commercial release is estimated to be 2013.

The rapid adoption of GE corn in the Philippines has encouraged continued product research and development. Monsanto is currently field-testing the second "generation" of the current Bt and RR corn. The Bt corn currently being tested reportedly has been modified to produce the *bacillus thuringiensis* while the RR variety has been altered to be resistant to the Roundup herbicide.

The following table shows U.S. exports to the Philippines last year that possibly were derived from modern agricultural biotechnology. Trade value last year was approximately \$227 million with soybean-based products accounting for the majority share (68 percent). U.S. exports to the Philippines in 2009 grew 3 percent from the previous year's level with GE cotton posting the greatest increase (112 percent).

CY US Exports to th	ne Philippines (
Commodity Group	2007 2008		2009	% Ch	ange
				07/08	08/09
Soybean Meal	89,011,423	144,950,321	146,144,977	62.84	0.82
Feeds & Fodders	31,025,149	42,580,387	42,931,449	37.24	0.82
Soybeans	17,711,335	10,465,392	8,050,652	-40.91	-23.07
Sweeteners	5,354,038	11,377,484	7,653,716	112.50	-32.73
Coarse Grains	1,472,934	2,227,773	3,004,186	51.25	34.85
Cotton	12,063,216	8,998,436	19,060,443	-25.41	111.82
Vegetable Oil*	1,218	1,313	1,127	7.80	-14.17
Soybean Oil	177	219	80	23.73	-63.47
TOTAL	156,639,490	220,601,325	226,846,630	40.83	2.83

^{*} excluding soybean oil

Source of Basic Data: Global Trade Atlas

The current biotechnology regulations require all shipments of regulated articles to the Philippines to be accompanied by a corresponding declaration of genetically modified organism (GMO) content. The GMO declaration may be issued by a responsible officer from the country of origin; an accredited laboratory; the shipper; and/or the importer. A list of these regulated articles is provided in the following link:

http://www.biotech.da.gov.ph/upload/annexIII.pdf

Section III. Plant Biotechnology Policy:

Philippine policy on modern agricultural biotechnology continues to evolve but is anchored on sound science. The current regulatory regime is embodied in the DA-AO 8. The responsible Philippine government regulatory agencies and their roles in relation to Philippine biotechnology regulations remain unchanged as reported in GAIN RP 5027. The BPI continues to be the lead-agency in implementing DA-AO 8.

Under the current regulations, 31 TEs have been approved for food, feed or processing materials (see Appendix A), marginally higher than the 30 approved TEs posted in the previous annual report. In addition, there were approved 22 stacked trait products as of May 4, 2010, up from the 18 approved products reported in the previous annual report. A summary of approved stacked or combined trait products follows:

SUMMARY OF APPROVED COMBIN PRODUCTS	ED TRAIT	
As of May 4, 2010		
Combined Trait Product	Technology Developer	Date Approved * Renewal
1. Corn MON810 x Corn NK603 **	Monsanto	*1/8/2010
2. Corn NK603 x Corn MON863	Monsanto	*1/8/2010
3. Corn MON810 x Corn MON863	Monsanto	*1/8/2010
4. Corn MON810 x GA21	Monsanto	*2/8/2010
5. Cotton 531 x Cotton 1445	Monsanto	*1/8/2010
6. Cotton 15985 x Cotton 1445	Monsanto	*1/8/2010
7. Corn MON863 x MON810 x Corn NK603	Monsanto	*2/05/2010
8. Corn TC 1507 x Corn NK603	Pioneer	02/17/06
9. Cotton 15985 x Cotton 88913	Monsanto	04/20/06
10. Corn MON 88017 x Corn MON 810	Monsanto	07/03/06
11. Corn LY038 x Corn MON 810	Monsanto	08/03/06
12. Corn DAS 59122 x Corn NK603	Pioneer	12/20/06
13. Corn Bt 11 x Corn GA21	Syngenta	01/23/07

14. Corn TC1507 x Corn DAS 59122	Pioneer	01/23/07
15. Corn DAS59122 x Corn TC1507	Pioneer	02/07/07
x Corn NK603		
16. Corn Bt11 x Corn MIR 604	Syngenta	12/13/07
17. Corn MIR 604 x Corn GA21	Syngenta	12/13/07
18. Corn Bt11 x Corn MIR 604 x GA21	Syngenta	03/03/08
19. Corn MON89034 x Corn NK603	Monsanto	07/22/09
20. Corn MON89034 x Corn	Monsanto	10/19/09
MON88017		
21. Corn MON89034 x Corn 1507	Monsanto	02/02/10
x Corn 88017 x Corn 59122		
22. Corn NK603 x Corn T25	Monsanto	04/22/10

^{**} Approved for propagation

On the area of labeling, although the Philippine Health Department's Food and Drug Administration (formerly Bureau of Food and Drugs) has made known its support for a voluntary labeling regime, it has yet to release formal labeling guidelines that apply to processed foods derived from the use of modern biotechnology.

The Philippines, being strategically situated in the region, has made known its desire to be a player in the lucrative halal food market. Halal is a term used to designate food seen as permissible according to Islamic law (Sharia,). In 2005, unconfirmed reports estimate the global halal market at about \$2.8 trillion. Whether biotechnology derived foods are permissible under Islamic dietary guidelines (halal foods), however, have not yet been established. This has been the subject of discussions and in early 2008 the Philippine Bureau of Product Standards issued the Philippine National Standards (PNS) on Halal Food. The PNS during that time carried a provision that foods derived from modern biotechnology are not subject to halal certification until more knowledge and understanding on its safety is attained.

Recently, there have been moves to amend the PNS specifications to make foods derived from modern biotechnology subject to halal certification. In response, the Biotechnology Coalition of the Philippines (BCP) has been conducting seminars arguing that if the source of the inserted gene (the donor organism) is halal, the food derived from the product can be certified as halal based on the current halal certification process. A resolution has yet to be reached, however.

Agricultural policy is intimately intertwined with politics in the Philippines and national and local elections were held on May 10, 2010. A newly elected government officially assumed office in July 1,

2010 and President–elect Benigno Aquino III is perceived to be pragmatic. Although policy directions relative to modern agricultural biotechnology are still unknown, Post, in general terms, does not expect any significant deviation in overall Philippine agricultural policy.

Section IV. Plant Biotechnology Marketing Issues:

IV. Marketing Issues

While the overall support on the responsible use of modern agricultural biotechnology remains to be strong, there are pockets of resistance. Despite outreach efforts by the local DA, the provincial GMO ban imposed last year by the province of Negros Occidental remains in effect. Shortly before the May 10 elections, the neighboring province of Negros Oriental imposed a similar ban. Both provinces are major sugar producing areas.

With regards to current L & R discussions in relation to the CPB, the Philippines approaches the issue from both a technology-user perspective as well as a technology-developer point of view. As such, local concerns are focused on Article 3 (which deals on scope) and on Article 10 (financial security). Regarding the former, contacts from the local DA contend that the term "products thereof" in Article 3 falls beyond the scope of the CPB. On the other hand, the language used on financial security is non-obligatory and too permissive, according to the same contact, and that more "binding" language is preferred.

Section V. Plant Biotechnology Capacity Building and Outreach:

The IPB-UPLB is the country's premier agricultural biotechnology research agency and is located in the state university's campus. Classes for the first semester of school year 2010/2011 in UPLB opened about a month ago and for the first time, a Bachelor of Science Degree in Agricultural Biotechnology was offered. The 4-year undergraduate program will help ensure that agricultural biotechnology research will continue to flourish. This will also help maintain the country's regional biotechnology leadership status.

In general terms, the biotechnology and biosafety short courses offered by the Michigan State University under the Cochran Fellowship Program continues to be the primary USDA biotechnology capacity building activity for Philippine regulators, technical personnel and policy makers. Related training under the Norman E. Borlaug International Agricultural Science and Technology Fellowship Program has also helped. The Philippines is becoming a popular destination of foreign delegations interested to learn how to establish biotechnology regulations systems as well as observe local current research and development efforts.

From July 5-9, 2010, Post working closely with FAS Jakarta and the BCP, help organize and accompanied a 13-man delegation from Indonesia on a biotechnology exposure trip to selected GE corn farms in the island of Mindanao. Prior to this, the delegation visited biotechnology research facilities of the International Rice Research Institute and ongoing field tests of the IPB-UPLB. The successful visit culminated with a courtesy call on Philippine DA officials. There are recent indications that a follow up to this activity is forthcoming soon.

Post is also currently working on a FY2010 EMP agricultural biotechnology regulatory outreach activity that will bring local regulators to the United States for a training update. This project is a sequel to the highly successful EMO-TIRF funded biotech training activity in 2003 held at the APHIS headquarters in Riverdale which featured experts from the FDA, EPA and APHIS.

Section VI. Animal Biotechnology:

There are currently no Philippine research and development projects on transgenic animals.

Section VII. Author Defined:

APPENDIX A

APPROVAL REGISTRY FOR THE IMPORTATION OF REGULATED ARTICLES FOR DIRECT USE FOR FOOD, FEED & FOR PROPAGATION						
as of March	<u> </u>				sessment	
Event	Introduced trait and gene	Date Approved	Food	Feed	Propagation	Developer
1. Corn MON 810	Contains <i>cry1A(b)</i> gene from <i>Bacillus thuringiensis</i> var. <i>kurstaki</i> which confers resistance to corn borer	* 12/03/07	X	X	X	Monsanto
2. Corn Bt	Contains the cr1Ab gene from Bacillus thuringiensis and pat gene from Streptomyces viridochromogenes which confers resistance to corn borer tolerance to herbicide, respectively	* 7/22/08	X	X	X	Syngenta
3. Soybean 40-3-2	Contains <i>cp4epsps</i> coding sequence from <i>Agrobacterium</i> sp. Strain, CP4 which confers resistance tolerance to Roundup family of agricultural herbicides	* 7/22/08	X	X		Monsanto

4. Corn NK 603	Contains <i>cp4epsps</i> coding sequence from <i>Agrobacterium</i> sp. CP4 strain which confers resistance tolerance to Roundup family of agricultural herbicides	* 09/10/08	x	х	X	Monsanto
5. Corn MON 863	Contains cry3Bb1 gene from Bacillus thuringiensis subsp kumamotoensis which contains resistance to the corn root worm	* 10/07/08	х	Х		Monsanto
6. Corn TC 1507	Contains cry1F Bacillus thuringiensis (Bt) var. aizawai, and pat genes from Streptomyces vindochromogenes controlling certain lepidopteran pests such as European corn borer, southwestern corn borer, fall armyworm and black cutworm, and conferring tolerance to glufosinate ammonium herbicides, respectively.	* 10/07/08	x	x		Pioneer
7. Corn DBT 418	Contains cry1Ac gene from Bacillus thuringiensis subsp kurstaki and the bar gene from Streptomyces hygroscopicus that confers resistance to lepidopteran insects and tolerance to herbicide	* 10/22/08	X	X		Monsanto

	phosphinotricin respectively.					
8. Canola RT 73	Contains cp4epsps coding sequence from Agrobacterium sp. CP4 strain and the GOXv247 coding sequence from Ochrobactrum anthropi strain LBAA that confers tolerance to the Roundup family of agricultural herbicides	* 10/22/08	X	X		Monsanto
9. Corn BT 176	Contains cry1Ab gene from Bacillus thuringiensis var kurstaki which confers resistance to lepidopteran insect pest and bar gene from Streptomyces hygroscopicus, which produces an enzyme, phosphinothricin acetyl transferase (PAT)	* 10/24/08	X	X		Syngenta
10. Corn GA 21	Modified <i>epsps</i> gene from corn which confers tolerance to herbicides	*11/20/08	x	X	X	Monsanto
11. Corn DLL25	Contains the bar gene from bacterium, Streptomyces hygroscopicus that confers tolerance to herbicide phosphinotricin	*11/20/08	X	X		Monsanto
12. Corn T25	Contains <i>pat</i> gene fro Streptomyces viridochromogenes	* 12/05/08	Х	Х		Bayer Crop Science

	which encodes for tolerance to herbicide , phosphinotricin				
13. Cotton 1445	Contains <i>cp4epsps</i> coding sequence from <i>Agrobacterium</i> sp strain, CP4 which confers tolerance to the Roundup family of agricultural herbicides	* 12/05/08	X	X	Monsanto
14. Cotton 15985	Contains the <i>cry2Ab2</i> and <i>cry1Ac</i> genes which encode proteins that convey protection from lepidopteran insect pests	* 12/05/08	X	X	Monsanto
15. Potato Bt6 (RBBT 02-06) and SPBT 02-05	Contains <i>cryIIIA</i> coding sequence from <i>Bacillus thuringiensis</i> subsp <i>lenebriones</i> for tolerance to Colorado potato beetle	* 12/05/08	X	x	Monsanto
16. Potato RBMT 15- 101, SEMT 15-02 and SEMT 15- 15	Contains cryIIIA coding sequence from Bacillus thuringiensis subsp lenebriones strain B1256-82, which confers resistance to Colorado potato beetle and the PVY coat protein (PVYcp) isolated from PVY infected potatoes which confers resistance to the potato virus Y (PVY)	* 12/22/08	X	X	Monsanto
17. Cotton 531	Contains cry1Ac gene from Bacillus thuringiensis var. kurstaki which	* 02/05/09	X	х	Monsanto

	confers <i>r</i> esistance to lepidopterous pests				
18. Potato RBMT21- 129, RBMT21- 350 and RBMT 22- 82	Resistance to Colorado potato beetle - CryIIIA coding sequence, Resistance to potato leaf roll virus (PLRV) - PLRV replicase	*10/16/09	x	X	Monsanto
19. Sugarbeet H7-1	Contains <i>cp4epsps</i> coding sequence from <i>Agrobacterium sp.</i> CP4 strain, CP4 which confers tolerance to glyphosate	07/28/05	X	X	Monsanto
20. Cotton MON 88913	Cotton contains the <i>cp4epsps</i> coding sequence from <i>Agrobacterium sp.</i> Strain, CP4 which confers tolerance to the Roundup family of herbicides	11/29/05	X	X	Monsanto
21. Corn MON 88017	Contains cry3Bb1 gene from Bacillus thuringiensis subsp. Kumamotoensis, which confers resistance to the corn rootworm, Diabrotica spp and cp4epsps gene from Agrobacterium sp., which encodes tolerance to glyphosate resistance	03/08/06	X	X	Monsanto
22. Corn LY038	Contains <i>cordapA</i> coding sequence which is under control of the maize Glb1	05/19/06	X	X	Monsanto

	promoter that expresses the Corynebacterium glutamicum derived lysine insensitive dihydrodipcolinate synthase enzyme in the germ to increase the level of lysine in grain for animal feed applications.				
23. Alfalfa J101 and J163	Contains <i>cp4epsps</i> coding sequence from <i>Agrobacterium sp.</i> Strain, CP4 which confers tolerance to the Roundup family of agricultural herbicides	08/09/06	x	X	Monsanto
24. Corn 59122	Contains cry34Ab1 and cry35Ab1 from Bacillus thuringiensis which confers resistance to certain coleopteran pests such as corn rootworm, Diabrotica sp. And the pat gene from Streptomyces viridochromogenes which provides tolerance to glufosinate- ammonium herbicides.	08/09/06	X	X	Pioneer
25. Corn MIR604	Contains modified cry3A from Bacillus thuringiensis subsp. tenebriones which confers resistance to corn rootworm.	10/08/07	x	x	Syngenta
26. Soybean MON	Contains <i>cp4epsps</i> coding sequence from	11/16/07	X	X	Monsanto

89788	Agrobacterium sp Strain, CP4 which confers resistance tolerance to Roundup family of agricultural herbicides				
27. Corn 3272	Expresses a synthetic thermostable alpha amylase protein AMY797E that catalyzes the hydrolysis of starch into soluble sugars	02/07/08	х	X	Syngenta
28. Soybean A2704-12	Contains <i>pat</i> gene which confers tolerance to glufosinate ammonium herbicide	01/23/09	X	Х	Bayer CropScience
29. Corn MON89034	Contains two genes (cry1A.105 and cry2Ab2) from Bacillus thuringiensis which protects the plant from Asiatic corn borer, common cutworm and corn earworm	04/29/09	x	X	Monsanto
30. Soybean DP356043	Contains the <i>gat4601</i> gene derived from <i>Bacillus licheniformis</i> conferring tolerance to glyphosate and ALS (acetolactate synthase) inhibiting herbicides	11/26/09	X	X	Pioneer
31. Corn MIR162	Contains two novel genes: <i>vip3Aa20</i> gene from <i>Bacillus thuringiensis</i> resistance to lepidopteran pests and	02/11/10	X	X	Syngenta

pmi gene from		
Escherichia coli encoding the enzyme		
phosphomannose		
isomerase present as a selectable marker		

^{*} Renewal